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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,020	02/14/2002	Kiyoshi Taniguchi	219501US0CONT	6207
22850	7590	02/07/2006	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			COPPINS, JANET L	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 02/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/074,020	Applicant(s) TANIGUCHI ET AL.	
	Examiner Janet L. Coppins	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-18, 21-43 and 46-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10-18, 22-43, 46 and 47 is/are allowed.
- 6) ☒ Claim(s) 48 is/are rejected.
- 7) ☒ Claim(s) 21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/646,878.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 10-18, 21-43, and 46-48 previously allowed by Examiner Covington in the Notice of Allowance mailed August 24, 2005.

Prosecution Reopened

1. Pursuant to the Notice of Withdrawal from Issue under 37 CFR 1.313(b), sent out September 9, 2005, prosecution on the merits of this application is reopened on claims 21 and 48, considered unpatentable for the reasons indicated below:

Objection- Double Patenting

2. Claim 21 objected to under 37 CFR 1.75 as being a substantial duplicate of claim 10. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Both claims recite a method of treating a subject having dysuria.

Claim Rejections - 35 USC § 112

3. Claims 48 is drawn to a method for inducing lypolysis, by administering a compound of the instant claims.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 48 rejected under 35 U.S.C. 112, first paragraph, as not being fully enabled. While various urinary tract disorders may be listed in the specification, the claims are not enabled for *all* disorders responsive to the induction of lipolysis, since there is no indication as to the full

Art Unit: 1626

range of disorders that could be treated using the instant claimed method.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

In the instant case, the claims are directed to many disorders and conditions that are not enabled in the specification, including those broadly covered in claim 48.

The nature of the invention

Claim 48 is directed to a method of ameliorating a pathology. However, claim 48 is a reach-through claim, drafted in terms of an interaction between molecules, which is not a specific utility such that one skilled in the art would know how to perform the claimed method for treating a specific disease or diseases.

The state of the prior art and the predictability or lack thereof in the art

It is well recognized in the medical art that treatment of diseases or symptoms are not analogous terms. The nature of pharmaceutical arts is that it involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face. Also, in the absence of a showing of correlation between *all* the disorders claimed as capable of being treated by the

Art Unit: 1626

compound of the instant claims and the response of lipolysis, one of skill in the art is unable to fully predict possible results from the administration of the claimed compounds.

***The amount of direction or guidance present and
the presence or absence of working examples***

The specification also only discusses three basic compounds in *in vitro* rat and dog assays which describe their inhibitory effects on intravesical pressure and bladder contractions on pages 42-46, and provides no further data for describing the efficacy of the claimed compounds for treating the full scope of disorders that are encompassed by inducing lypolysis.

The breadth of the claims

Applicants are claiming a method of inducing lypolysis, which encompasses a broad number of diseases or conditions. The argument that the diseases claimed by the Applicants are all treated by inducing lypolysis is insufficient support that the claimed compounds have specific efficacy in current available form for treating all of the disorders and conditions encompassed by the broadly recited claim 48.

The quantity of experimentation needed

The quantity of experimentation needed is undue. One of ordinary skill in the art without direction, would be unable to treat each and every disease/condition encompassed by claim 48, using the instant claimed compounds. One of skill in the art would need to determine what diseases would be benefited by inducing lypolysis and would furthermore then have to determine whether the claimed compounds would provide treatment of all of the disorders and conditions by said activity. Based on the unpredictable nature of the invention and the state of the prior art and the breadth of the claims, one of ordinary skill in the art would be burdened with undue

Art Unit: 1626

“experimentation study” to determine whether the claimed compounds not only induce lypolysis, but also treat disorders of real-world relevance.

The level of the skill in the art

The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by *in vitro* and *in vivo* screening to determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

The Examiner suggests claiming the possible disorders or conditions that are treated, rather than claiming the mechanism, which is speculative, and recommends the following language, “A method of inducing lypolysis, for treating _____, comprising administering to a patient in need thereof, a therapeutically effective amount of a compound of claim 36....”

6. Applicant is advised that the Notice of Allowance mailed is vacated. If the issue fee has already been paid, applicant may request a refund or request that the fee be credited to a deposit account. However, applicant may wait until the application is either found allowable or held abandoned. If allowed, upon receipt of a new Notice of Allowance, applicant may request that the previously submitted issue fee be applied. If abandoned, applicant may request refund or credit to a specified Deposit Account.

Art Unit: 1626

Conclusion

7. In conclusion, claims 10-18, 21-43, and 46-48 are pending, claims 10-18, 22-43, 46, and 47 are allowable, claim 21 is objected to, and claim 48 is rejected.

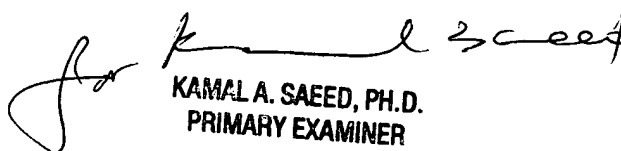
Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Coppins whose telephone number is 571.272.0680. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571.272.0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Coppins
February 3, 2006


KAMAL A. SAEED, PH.D.
PRIMARY EXAMINER